DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P O Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone 303-236-3000
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November 6, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Richard Allen
General Manager
LDS Dairy Operations
P.O. Box 10
Elberta, Utah 84626

Ref. #: DEN-03-05

Dear Mr. Allen:

Consumer Safety Officers Betty Kay Baxter and Debra L. Curtis conducted an inspection at your dairy farm, Fort Lupton Dairy, 3421 CR 31, Fort Lupton, CO, on July 8-10, 2002. The inspection confirmed that you offered animals for sale for slaughter as food, in violation of sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), and that you caused animal drugs to become adulterated within the meaning of section 501(a)(5) of the Act.

Specifically, you sold dairy cows on three separate occasions to [redacted] which were found to contain illegal levels of drug residues by U.S. Department of Agriculture (USDA) testing.

These three incidents, recorded under USDA case No. 01-1589-CO include:

October 9, 2001: USDA analysis of tissue samples collected from your dairy cow with tag [redacted] (USDA Sample No. 410963) identified the presence of Gentamicin sulfate residue of 14.31 ppm in the kidney and 0.85 ppm in the liver. No tolerance has been established for residues of Gentamicin sulfate in the edible tissues of dairy cattle in Title 21 Code of Federal Regulations Part 556.300 (21 CFR 556.300).

October 11, 2001: USDA analysis of tissue samples collected from your dairy cow with tag X (USDA Sample No. 410965) identified the presence of Gentamicin sulfate residue of 18.80 ppm in the kidney, and 0.17 ppm in the liver.

October 23, 2001: USDA analysis of tissue samples collected from your dairy cow with tag X (USDA Sample No. 410966) identified the presence of Gentamicin sulfate residue of 9.00 ppm in the kidney and 2.87 ppm in the liver.

Our investigation revealed the use of GentaMax 100 (Gentamicin Sulfate Solution). There is no allowable tolerance established for residues of gentamicin sulfate solution in edible tissues of cattle. The presence of this drug in edible tissue from these animals causes the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) of the Act.

Our investigation also found that you hold animals under conditions which are inadequate to prevent diseased and/or medicated animals bearing potentially harmful drug residues from entering the food supply. For example, animal treatment records are inadequate or incomplete and controls are not in place to assure the correct medication is administered. In addition, you lack an adequate system for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions are adulterated within the meaning of section 402(a)(4) of the Act.

We note that the residues were reportedly caused by the mistaken use of Gentamicin Sulfate instead of Flunixin Meglumine (Banamine) due to similar labels. However, two of the dairy cows were shipped to slaughter within one day of treatment although the label for Banamine requires a minimum of four days withdrawal. Even if Banamine was administered, the required withdrawal period would not have been observed.

Our investigation also determined that X additional dairy cows may have been treated with GentaMax 100. During the inspection, you advised the investigators that X of these cows died and that you would withhold X of these cows (XXXX) from slaughter for one year from their treatment dates. You also told the investigators that you would not withhold the X remaining cows (XXXXX) from slaughter because they may have been treated with the correct medication. Our inspection found you have no justification to support this position.

You are adulterating the drug GentaMax 100 brand of Gentamicin Sulfate Solution that your firm uses on dairy cows within the meaning of section 501(a)(5) of the Act when you fail to use the drug in conformance with its approved labeling. There is no labeled use of GentaMax 100 in beef or dairy cattle. Your use of the drug without following the labeling causes the drug to be unsafe for use.

As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law. Failure to do so may result in regulatory action without further notice such as seizure, and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

By copy of this Warning Letter, we are advising USDA/Food Safety Inspection Service to monitor the slaughter of cows for a minimum of eighteen months. We strongly suggest that you withhold these cows from slaughter to allow for depletion of potentially hazardous residues.

You should notify this office in writing within 15 working days of the steps you have taken to bring your operation into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 30 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be sent to H. Tom Warwick, Compliance Officer, Food and Drug Administration, P.O. Box 25087, Denver, Colorado, 80225-0087. He may be reached at (303) 236-3054 if you have any questions about this matter.

Sincerely,

Susan J. Miller for

B. Belinda Collins
District Director

cc: Mr. Ronald K. Jones
D.V.M.
Boulder District Manager
USDA/FSIS
665 S. Broadway, Suite B
Boulder, CO 80303

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